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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,843	11/18/1999	PAUL JARRETT		1574

110 7590 11/25/2005

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EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/242,843

Applicant(s)

JARRETT ET AL.

Examiner

Sean R. McGarry

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/22/05 [9/24/03].
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37 and 42-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37 and 42-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 37, 42-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection and is maintained for those reasons set forth in the official action mailed 3/29/01 and 11/20/01 and 5/06/03.

The instant invention is broadly drawn to an pesticidal composition that comprises at least one of cells into which a nucleotide sequence of SEQ ID NO: 1 has been introduced or a cellular extract from such cells where the cells and extract have toxicity when administered orally to an insect. SEQ ID NO: 1 is a nucleic acid sequence of almost 40kb. The specification, for example, indicates that this sequence may contain **more than one protein coding sequence that may be insecticidal either alone or when presented together** (see page 3, lines 10-15). The specification does not provide one in the art what the coding sequence/s may be within this large piece of DNA or what the **sequence or structure of the protein or proteins is/are or whether there are in fact two or more proteins that may or may not be needed to provide for an insecticidal activity**. The specification has therefor not provided a functional characteristic coupled with a known or disclosed correlation between function and structure. The disclosure of a large nucleic acid sequence does not provide the structure of a pesticidal proteinaceous material that may be composed of various components and or that may be processed (see page 3, lines 10-15, for example). The

Art Unit: 1635

specification does not indicate from what reading frame the protein or proteins may be expressed from SEQ ID NO: 1. The specification only provides rudimentary qualities to **supernatants and extracts** (supernatants and extracts are not of equivalent scope to a "composition that may comprise a proteinaceous material obtainable from *Xenorhabdus nematophilus*") such as stability and the retention and loss of activity in filters as different as 40kDa and 100 kDa.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 1 as a whole (ie a cell transformed with the sequence of SEQ ID NO:1 and extracts from such cells), the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides (that may encode the active components encompassed within the whole of SEQ ID NO: 1) and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and **reference to a potential method for isolating it**. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack

of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an

Art Unit: 1635

adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

It appears that the specification, as filed, provides a starting point for one in the art to make a determination of a structure function relationship i.e a plan or first step for obtaining a desired result.

I. Applicant's arguments filed 9/24/03 and 8/22/05 have been fully considered but they are not persuasive and are repeated below.

Applicant assert at page 8 of the response filed 9/24/03 that the invention is limited to cells "which are transformed with the nucleotide sequence of SEQ ID NO: 1 and supernatants of such cells" . It is noted that the claims are not limited to the nucleotide sequence, but to a nucleotide sequence of SEQ ID NO:1.

Applicant argues that SEQ ID NO: 1 provides a structure for written description. Applicant argues that they have provided a reference sequence SEQ ID NO: 1 which applicant asserts provides toxicity to insects. This is not disputed. Applicant has shown that cellular extracts from organisms expressing SEQ ID NO: 1 have toxicity to insects. The claims as now amended require only a sequence from SEQ ID NO: 1 be introduced into a cell. This is different from a cell having SEQ ID NO: 1. As stated in the rejection, the specification has provided no guidance as to what sequence/s within SEQ ID NO: 1 is/are responsible for the observed function of insect toxicity. The specification does not provide a structure function relationship such that one in the art would recognize that applicant was in possession of portions of SEQ ID NO: 1 (ie a nucleotide sequence of . . . SEQ ID NO: 1) that are known to have the function of insect toxicity. The only composition disclosed is a cellular extract that possesses such a composition where the extract was made from cell where the entirety of SEQ ID NO: 1 have been introduced. Applicant argues that the specification provides a method that may allow one in the art to determine the protein or proteins responsible for the observed activity. It is noted that

Art Unit: 1635

an adequate written description of an invention requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; it requires a description of the compound itself (See *Fiers* 984 F.2d at 1170). It is clear that a method of potential isolation of a compound is not a substitute for a description of the claimed protein.

Applicant has argued previously that their subsequent work provides evidence that the specification provides a written description of the invention. It is noted that the publication appears to indicate that the specification, as filed, clearly did not provide a description of the claimed invention since it appears that much experimentation was performed to determine what protein of many potential proteins and further combinations thereof provided for insecticidal activity. It is noted that applicant subsequent work states at page 2067 "[t]he high level of expression of the xptA1 (which, for example, has not been disclosed in the instant specification) gene from the bacteriophage P_L promoter may be responsible for our ability to detect insecticidal activity for this single toxin". This statement is made in the context that it is typically for the insecticidal activity to be dependent from more than one protein. The instant specification does not disclose the combination of any protein for toxicity and clearly does not disclose using the bacteriophage P_L promoter to detect activity of the xptA1 protein.

II. Claims 37, and 42-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of culture medium and cells that contain SEQ ID NO: 1 as insecticidal compositions, does not reasonably provide enablement for the scope instantly claimed [sequences of SEQ ID NO: 1]. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The instant invention is broadly drawn to a composition which is a cell or culture therefrom where a nucleotide sequence of SEQ ID NO: 1 has been introduced into the cell.

The instant specification describes the use of cells and supernatant to kill insects. The instant specification does not disclose the killing of any insect via the ingestion of a proteinaceous compound per se but only shows inhibition of growth and death via cells per se and from supernatant. The instant specification does not provide one in the art with guidance for what specific agent is responsible for the death of insects but teaches only that within a 40kb DNA something or things is encoded that causes death of insects. The specification, for example, indicates that this sequence [SEQ ID NO:1] may contain more than one protein coding sequence that may be insecticidal either alone or when presented together (see page 3, lines 10-15). The specification does not provide

Art Unit: 1635

one in the art what the coding sequence may be within this large piece of DNA or what the sequence or structure of the protein or proteins is/are or whether there are in fact two or more proteins that may or may not be needed to provide for an insecticidal activity. The specification only provide rudimentary qualities to supernatants and extracts such as stability and the retention and loss of activity in filters as different as 40kDa and 100 kDa. It is unclear from the disclosure what specific compound or combination of compounds is responsible for the insecticidal activity observed from the application of supernatant or cells per se. The instant specification does not point with any particularity to any specific compounds such as those that are claimed. One in the art would be required to make that determination in the practice of the instant invention. One in the art would not know what the structure of such a composition would be based on the general disclosure provided. One in the art would be required to perform undue trial and error experimentation to practice the instant invention. The Quantity of experimentation would include, for example, determine what sequence/s within SEQ ID NO: 1 code for protein or proteins that provide for pesticidal properties (for example is it one protein or a combination of two or more, does the protein itself provide toxicity or does the protein convert some substrate into a toxic substance and is this substrate from the cells per se or from the medium provided for growth?). The specification teaches one in the art how to use a cell per se and how to use a supernatant [made from a cell that contains all of SEQ ID NO: 1] in the killing of insect pests. The instant specification does not teach one how to make or use any of the particular sequences that may be contained within SEQ ID NO: 1.

III. Applicant's arguments filed 2/19/03 have been fully considered but they are not persuasive.

Applicant assert at page 8 of the response filed 9/24/03 that the invention is limited to cells "which are transformed with the nucleotide sequence of SEQ ID NO: 1 and supernatants of such cells". It is noted that the claims are not limited to the nucleotide sequence, but to a nucleotide sequence of SEQ ID NO:1.

Applicant has argued previously that their subsequent work provides evidence that the specification provides a written description of the invention. It is noted that the publication appears to indicate that the specification, as filed, clearly did not provide a description of the claimed invention since it appears that much experimentation was performed to determine what protein of many potential proteins and further combinations thereof provided for insecticidal activity. It is noted that applicant subsequent work states at page 2067 "[t]he high level of expression of the xptA1 (which, for example, has not been disclosed in the instant specification) gene from the bacteriophage P_L promoter may be responsible for our ability to detect insecticidal activity for this single toxin". This statement is made in the context that it is typically for the insecticidal activity to be dependent from more than one protein. The instant specification does not disclose the combination of any protein for toxicity and clearly does not disclose using the bacteriophage P_L promoter to detect activity of the xptA1 protein.

Claim 37 is objected to because of the following informalities: At line two, it appears that " at lease" is a typographical error and was intended to read "at least". At line 5, it appears that the term "have" was intended to be "has" since it refers to a singular "nucleotide sequence". Appropriate correction is required.

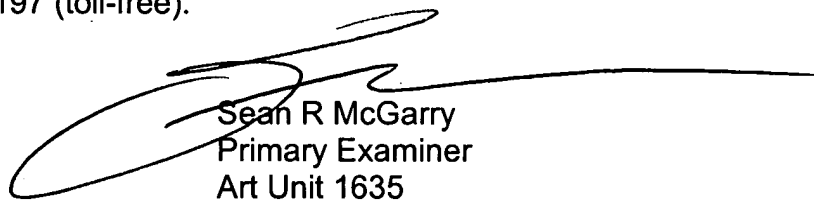
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sean R McGarry
Primary Examiner
Art Unit 1635